



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P O Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| | | | | |
|---|-------------|----------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/905,683 | 07/16/2001 | Jamie M. Grooms | 197319US/222962US | 4376 |
| 52727 | 7590 | 11/16/2009 | EXAMINER | |
| REGENERATION TECHNOLOGIES, INC. c/o MCANDREWS, HELD & MALLOY 500 WEST MADISON STREET 34TH FLOOR CHICAGO, IL 60661 | | | SNOW, BRUCE EDWARD | |
| ART UNIT | | PAPER NUMBER | | |
| 3738 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 11/16/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JAMIE M. GROOMS, KEVIN C. CARTER, TOM SANDER and
DAVID H. DULEBOHN

Appeal 2009-014427
Application 09/905,683
Technology Center 3700

Decided: November 16, 2009

Before: WILLIAM F. PATE III, JENNIFER D. BAHR and
LINDA E. HORNER, *Administrative Patent Judges*.

PATE III, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF CASE

Appellants appeal under 35 U.S.C. § 134 from a rejection of claims 111-118 and 120-136. We have jurisdiction under 35 U.S.C. § 6(b). This Appeal is related to Appeal number 2009-000600 in Application number

Appeal 2009-014427
Application 09/905,683

10/387,322 and Appeal number 2009-006360 in Application number 09/782,594.

The claims are directed to an assembled bone implant suitable for implantation into a patient. Claim 111, reproduced below, is illustrative of the claimed subject matter:

111. An assembled bone implant suitable for implantation into a patient comprising:

a first cortical bone portion;
a second cortical bone portion;

said first cortical bone portion and said second cortical bone portion having one or more circular through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and

one or more retention pins of appropriate diameter for fitting said through holes and connecting said first cortical bone portion to said second cortical bone portion and forming said assembled bone implant as a unitary body outside of said patient, said assembled bone implant being suitable for implantation into said patient.

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

| | | |
|-----------|-----------------|---------------|
| Brantigan | US 5,192,327 | Mar. 9, 1993 |
| Stroever | US 5,728,159 | Mar. 17, 1998 |
| Coates | US 5,989,289 | Nov. 23, 1999 |
| Siebels | EP 0 517 030 A2 | Dec. 9, 1992 |

Fred H. Albee, *Bone Surgery with Machine Tools*, Scientific American vol. 154, No. 4, April, 1936, pp. 178-181

Claims 111-118, 120-123, and 129-136 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Albee. Ans. 3.

Claims 111-118, 120-136 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Coates and Siebels. Ans. 4.

Claims 111-118, 120-136 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Brantigan and Coates. Ans. 5.

SUMMARY OF DECISION

The rejection of claims 111-118, 120-123, and 129-136 as being anticipated by Albee is reversed.

The rejection of claims 111-118, 120-125, and 129-136 as being unpatentable over Brantigan and Coates is reversed.

The rejection of claims 111-118, 120-136 as being unpatentable over Coates and Siebels is affirmed.

The rejection of claims 126-128 as being unpatentable over Brantigan and Coates is affirmed.

Our reasons follow.

THE REJECTION OF CLAIMS 111-118, 120-123, AND 129-136 AS BEING ANTICIPATED BY ALBEE

ISSUE

Appellants argue that Albee does not anticipate independent claims 111 and 129 because Albee fails to disclose an “assembled bone implant.” Appellants contend that the implant depicted in Figure 3, subfigure 10, of Albee is a single individual piece and not an assembled bone implant. App.

Br. 16-17, 22. The Examiner contends that the entire joint depicted in Figure 3, subfigure 10, of Albee may be extracted from one patient and implanted into a second patient. Ans. 7. In light of these contentions the first issue for our consideration is whether the Appellants have established that the Examiner erred by determining that the implant depicted in Figure 3, subfigure 10, of Albee may reasonably be interpreted as an “assembled bone implant.”

OPINION

“[T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant’s specification.” *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Appellants and the Examiner agree that one of ordinary skill in the art would understand the term “assembled” to require the implant to be formed from more than one piece. The Examiner, however, contends that the bones of the joint depicted in figure 3, subfigure 10, may be construed as part of the “bone implant.” We disagree. Appellants have consistently used the term “bone implant” to describe a structure placed between vertebrae not one that includes vertebrae. *See e.g.*, Spec. 1-3. One of ordinary skill in the art would not interpret the term “bone implant,” read in light of Appellants’ Specification, to include the structure of the bones themselves into, or between which the claimed device is implanted.

Since the Examiner based the rejection of claims 111 and 129 on an unreasonable interpretation of the scope of the claimed subject matter, we are constrained to reverse the rejection of claims 111 and 129, along with dependent claims 112-118, 120-123, and 130-136, as being anticipated by Albee.

**THE REJECTION OF CLAIMS 111-118, 120-125, AND 129-136 AS
BEING UNPATENTABLE OVER BRANTIGAN AND COATES**

ISSUES

Appellants argue that the Examiner erred in concluding that the subject matter of claim 111 would have been obvious over Brantigan and Coates because the Examiner improperly interpreted the grooves 14, 24, or the central aperture 11d, 21d, of Brantigan as a circular through hole. App. Br. 53-56; Reply Br. 7-8. The Examiner contends that since elements 14, 24 are semi-circular they are “of or relating to a circle” and are therefore “circular.” Ans. 12. Thus, the next issue for our consideration is whether Appellants have established that the Examiner erred by determining grooves 14, 24, or the central aperture 11d, 21d, of Brantigan may reasonably be interpreted as “circular.”

Appellants argue that the Examiner erred in concluding that the subject matter of claim 129 would have been obvious over Brantigan and Coates because the Examiner improperly interpreted Brantigan’s rectangular connect bar 15 as a “pin[] of appropriate diameter.” Reply Br. 8-9. The Examiner contends that the connecting bar 15 can be described as a pin having a diameter. Ans. 12. Thus, the next issue for our consideration is

whether Appellants have established that the Examiner erred by determining that the connecting bar 15 of Brantigan may reasonably be interpreted as a “pin[] of appropriate diameter.”

OPINION

In construing claim terms, the general meanings gleaned from reference sources, such as dictionaries, must always be compared against the use of the terms in context, and the intrinsic record must always be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor. “Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings.”

Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1300 (Fed. Cir. 2003) (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)); *Ferguson Beauregard/Logic Controls, Div. of Dover Resources, Inc. v. Mega Systems, LLC*, 350 F.3d 1327, 1338-39 (Fed. Cir. 2003).

The term circular is used by Appellants to describe the shape of the holes. Read in light of the Specification, one of ordinary skill in the art would have understood the term “circular through hole” to mean a hole that is shaped like or nearly like a circle. Since neither the semi-circular grooves 14, 24, the ovular (11d) or D-shaped (21d) apertures of Brantigan are shaped like or nearly like a circle they are not reasonably read as “circular through hole[s].”

When read in light of the Specification, the term “pin of appropriate diameter” would have been understood by one of ordinary skill in the art to

mean a pin having a single diameter, i.e., a cylindrical pin. Since the connecting bar 15 of Brantigan is not circular, it is not reasonably read as a “pin of appropriate diameter.”

Since the Examiner based the rejection of claims 111 and 129 on an unreasonable interpretation of the scope of the claimed subject matter, we are constrained to reverse the rejection of claims 111 and 129, along with dependent claims 112-118, 120-123, and 130-136, as being unpatentable over Brantigan and Coates.

**THE REJECTION OF CLAIMS 111-118, 120-136 AS BEING
UNPATENTABLE OVER COATES AND SIEBELS
ISSUES**

Appellants argue claims 111-113, 116-118, 120-121, 125-126, 129-131, and 134-136 as a group. App. Br. 33-48. We select claim 111 as the representative claim, and claims 112, 113, 116-118, 120-121, 125-126, 129-131, and 134-136 stand or fall with claim 111. 37 C.F.R. § 41.37(c)(1)(vii). Appellants argue claims 114, 115, 127, 132 and 133 as a group. App. Br. 33-48. We select claim 115 as the representative claim, and claims 114, 127, 132 and 133 stand or fall with claim 115. Appellants argue claims 123, 124 and 128 as a group. App. Br. 33-48. We select claim 124 as the representative claim, and claims 123 and 128 stand or fall with claim 124. Claim 122 is argued separately in the Reply Brief. Reply Br. 6-7.

The Examiner found that Coates discloses the structure of the implant comprising cortical bone described in claim 111 but fails to disclose assembling the implant from first and second portions connected by a pin. Ans. 4. The Examiner also found that Siebels demonstrates that it is known

in the art to manufacture the type of implants described by Coates from first and second portions connected by pins. *Id.* The Examiner concluded that it would have been obvious to use the technique taught by Siebels to construct the implant of Coates to thereby arrive at the claimed invention. *Id.*

Regarding the rejection of claim 111, the Appellants contend that the Examiner improperly relied upon conclusory statements without a rational underpinning in order to reach a conclusion of obviousness. App. Br. 33-35. Appellants further contend that the Examiner failed to properly consider the references as a whole, specifically, by ignoring portions of Siebels and Coates that would lead away from the claimed invention. App. Br. 35-43. Appellants further contend that there would not have been a reasonable expectation of success in combining the teachings of Siebels and Coates in the manner proposed by the Examiner. App. Br. 43-44. In light of these contentions, we must determine whether Appellants have established that the Examiner erred in concluding that the subject matter of claim 111 would have been obvious to one having ordinary skill in the art based on Siebels and Coates.

Regarding the rejection of claim 115, Appellants contend that the proposed combination would not have taught all the claimed elements because neither reference specifically teaches making a pin comprising cortical bone. App. Br. 44-46. In light of this contention, we must determine whether Appellants have established that the Examiner erred in concluding that the subject matter of claim 115 would have been obvious to one having ordinary skill in the art based on Siebels and Coates.

Regarding the rejection of claim 124, Appellants contend that the proposed combination would not have taught all of the claimed elements

because neither reference specifically teaches making a pin comprising cancellous bone treated with a bone morphogenetic protein (BMP). App. Br. 46-48. In light of this contention, we must determine whether Appellants have established that the Examiner erred in concluding that the subject matter of claim 124 would have been obvious to one having ordinary skill in the art based on Siebels and Coates.

Regarding the rejection of claim 122, Appellants contend that the proposed combination would not have taught all of the claimed elements because neither reference specifically teaches making an implant having a height between 7 and 14 mm. Reply Br 6-7. In light of this contention, we must determine whether Appellants have established that the Examiner erred in concluding that the subject matter of claim 122 would have been obvious to one having ordinary skill in the art based on Siebels and Coates.

FINDINGS OF FACT

1. Coates discloses a bone implant suitable for implantation into a patient. Col. 3, ll. 47-56
2. Coates demonstrates that it was known in the art to employ cancellous bone to construct implants. Coates remarks that the low compressive strength of cancellous bone makes it undesirable for use in constructing implants that are not used in conjunction with additional supporting structure, such as internal fixation. Col. 3, ll. 1-9.
3. Coates teaches providing an osteogenic composition, such as BMP, on the implant by injecting the composition into the implant, dripping it on the implant, or soaking the implant in it. Col. 8, ll. 9-32.

4. Coates suggests making implants any suitable size or shape and recognizes that cortical bone may be shaped to the desired configuration by conventional machining methods adapted to bone in a known manner. Coates, col. 11, ll. 52-64.
5. Coates does not criticize or discredit fabricating the implant from multiple pieces.
6. Coates teaches that because cortical bone exhibits high compressive strength as compared to other bone graft materials, it is a preferred material for use in constructing intravertebral implants 110. Coates recognizes that an allograft may be a suitable source for cortical bone. Coates, col. 2, ll. 61-62; col. 11, ll. 42-46.
7. Coates fails to disclose fabricating the implant by assembling a plurality of bone portions having circular through holes, connected with pins therein.
8. Siebels teaches an assembled implant 10 manufactured outside a body into which it is to be implanted (e.g., between vertebral bodies 50, 51). Siebels' implant has a modular design in order to enable the implant to be built to a desired height at the time of surgery. P. 4, ll. 18-25; p. 7, 1. 23 - p. 8, 1. 21; fig. 1.
9. Siebels teaches a plurality of stacked portions (e.g., disks 11-14) having circular through holes 16, and pins 17 therein to form the assembled implant 10. P. 8, ll. 11-21; p. 9, ll. 7-18.
10. Siebels teaches that the cross section of the disks is not limited to any particular form. For example, both round and rectangular disks may be used to fabricate the implant. P. 10, l. 13 – p. 11, l. 10; figs. 2, 6.

11. Siebels does not disclose that the disks 11-14 or pins 17 are made from cortical bone.
12. Siebels discloses that the disks 11-14 are preferably made from carbon-fiber reinforced plastic and the pins 17 may be constructed of the same or another material. P. 6, ll. 10-13. Siebels suggests that the disks can be manufactured from any biologically compatible material. P. 10, ll. 14-15.
13. Siebels does not criticize or discourage the use of cortical bone to construct the implants.

PRINCIPLES OF LAW

The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. The key to supporting any *prima facie* conclusion of obviousness under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) noted that the analysis supporting a rejection under 35 U.S.C. § 103 should be made explicit. The Federal Circuit has stated that “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), cited with approval in *KSR*, 550 U.S. at 418.

The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR*, 550 U.S. at 416. A *prima facie* conclusion of obviousness may be

supported by a showing that the claims are directed to a process, machine, manufacture, or composition of matter already known in the prior art that is altered by the mere substitution of one element for another known in the field, and such modification yields a predictable result. *See id.* (citing *United States v. Adams*, 383 U.S. 39, 40 (1966)). The Court further stated that “[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” *KSR*, 550 U.S. at 417. When considering obviousness of a combination of known elements, the operative question is thus “whether the improvement is more than the predictable use of prior-art elements according to their established functions.” *Id.*

Whether a reference teaches away from a claimed invention is a question of fact. *In re Harris*, 409 F.3d 1339, 1341 (Fed. Cir. 2005). “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, . . . would be led in a direction divergent from the path that was taken by the applicant.” *In re Haruna*, 249 F.3d 1327, 1335 (Fed. Cir. 2001) (quoting *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999)). “When a piece of prior art ‘suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the applicant’ the piece of prior art is said to ‘teach away’ from the claimed invention.” *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (quoting *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)). A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d

1540, 1550 (Fed. Cir. 1983). However, “the prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed....” *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

ANALYSIS

Coates discloses a bone implant suitable for implantation into a patient. Fact 1. Coates fails to disclose fabricating the implant by assembling a plurality of bone portions having circular through holes, connected with pins therein. Fact 7. Siebels teaches a plurality of stacked portions having circular through holes, and pins 17 therein, to form an assembled implant. Fact 9. Manufacturing Coates’ implant by Siebels’ method amounts to using a known technique to improve a known device in order to yield the predictable result of providing an implant that can be built to a desired height at the time of surgery (*see* Fact 8) and would have been obvious to one having ordinary skill in the art. Furthermore Coates expressly suggests that the size and shape of the implant may vary (*See* Fact 4) and Siebels suggests that his method may be applied to form implants of various shapes (*See* Fact 10).

Appellants argue that the Examiner relies upon only conclusory statements which are insufficient to establish a rationale underpinning to support the conclusion of obviousness. App. Br. 33-35. This argument is not persuasive. The Examiner reiterates the reason articulated in Siebels describing the advantages of Siebels’ technique. Ans. 4; *see* Fact 8. Furthermore, the references themselves articulate both a reason (*see* Fact 8)

and a suggestion (*see* Facts 4 and 10) to make the proposed modification. There is no basis to conclude that the Examiner improperly relied upon hindsight to reach a conclusion of obviousness.

Appellants further argue that because Siebels and Coates relate to different methods of making implants using different materials, one of ordinary skill in the art would have no basis to combine them. App. Br. 35-36; 38-39. In support of this argument Appellants point out that Coates does not describe assembled implants made from multiple pieces or connecting pieces using cortical bone, but instead requires a single-piece structure. App. Br. 36-37. Appellants further argue that because Siebels prefers manufacturing the implants from carbon-fiber reinforced plastic and recognizes that it is “easy” to do so, Siebels teaches away from fabricating the implant from cortical bone because cortical bone cannot be manufactured by those techniques Siebels would consider “easy.” App. Br. 39-41. Appellants’ arguments are not persuasive. The test for obviousness is not whether the claimed invention is expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have rendered obvious to those of ordinary skill in the art. *See In re Keller*, 642 F.2d 413, 425 (CCPA 1981). “Combining the teachings of references does not involve an ability to combine their specific structures.” *In re Nievelt*, 482 F.2d 965, 968 (CCPA 1973). It is not necessary to incorporate the specific material employed by Siebels when combining the teachings of Siebels with Coates. The fact that Coates criticizes some unclaimed aspect of Siebels, such as its use of synthetic materials, does not demonstrate that either references teaches away from the claimed invention or discredits fabricating the implant from multiple pieces.

Fact 5. Furthermore, merely disclosing a particular material, such as carbon-fiber reinforced plastic, as preferable would not lead one of ordinary skill in the art away from the use of an alternate material such as cortical bone, when reading the reference as a whole—especially when the reference specifically suggests that alternate materials may be employed. See Fact 12. The fact that a particular material exhibits desirable characteristics, such as ease of manufacturing, also would not lead one of ordinary skill in the art away from the use of alternate materials because one of ordinary skill in the art would recognize that alternate materials may also exhibit similar desirable characteristics. Appellants improperly interpret the teachings of Coates by concluding that Coates teaches that cortical bone is not a material that could be easily manufactured. The quoted portion of Coates on page 21 of Appellants' Brief describes the perceived difficulty in constructing an implant having the biomechanical properties of metal and the biological properties of bone without the disadvantages of either. This statement does not support Appellants' conclusion that Coates teaches it is extremely difficult or impossible to develop an implant from cortical bone. Firstly, the quoted portion of Coates is not discussing use of cortical bone, and secondly, the quoted portion of Coates is taken from the background discussion. The entirety of the reference evidences the state of the art, not only the background discussion. *See e.g., In re Lamberti*, 545 F.2d 747, 750, (CCPA 1976)(“The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain.”). As Appellants acknowledge, Coates does teach that conventional machining methods must be adapted to bone in order fabricate

the implant from cortical bone, but this does not suggest that the known manufacturing method described in Coates must be further modified to machine bone as Appellants assert. Rather, it suggests that Coates knew of conventional machines that have already been modified for this purpose. *See* Fact 4. Thus, one of ordinary skill in the art would not draw the conclusion from Coates that implants made from cortical bone would be particularly difficult to manufacture simply because they are made by techniques different from Siebels as Appellants suggest.

Appellants argue that no basis for a reasonable expectation of success has been established for combining Siebels and Coates. App. Br. 43-44. Appellants assert that because of the difficulties with making bone grafts as described in Coates, there would not have been a reasonable expectation of success that the implants could be assembled from multiple pieces. As noted above, however, one of ordinary skill in the art would not draw the conclusion from Coates that implants made from cortical bone would be particularly difficult to manufacture. Appellants further assert that Coates is directed to a single piece implant as opposed to multiple pieces, and while each of Siebels and Coates provide an implant of sufficient strength, neither reference provides a basis for concluding that the proposed combination would successfully provide this property. Again, the test for obviousness is not whether the claimed invention is expressly suggested in any one or all of the references. The fact that Coates does not specifically teach the use of cortical bone applied to an implant having multiple pieces pinned together does not establish that one of ordinary skill in the art would not have had a reasonable expectation of success in applying the cortical bone material taught by Coates to the implant disclosed in Siebels. Absolute predictability

that the substitution will be successful is not required. All that is required is a reasonable expectation of success. *See In re O'Farrell* 853 F.2d 894, 903-904 (Fed. Cir. 1988). Coates describes using known machining techniques to manufacture a structure from cortical bone which, from a machining standpoint, is more complex than the pins and disks described by Siebels due to its noncircular profile and asymmetry. This would have provided one of ordinary skill in the art with a reasonable expectation that the pins and disks of Siebels could also be manufactured from cortical bone. Siebels' suggestion to apply his modular technique to implants having various shapes would also have provided one of ordinary skill in the art a reasonable expectation that Siebels' technique could be applied to construct an implant such as the one depicted in Coates. Coates' description of the desirable structural characteristics of cortical bone would have provided one of ordinary skill in the art with a reasonable expectation than the pins and disks described by Siebels would posses the necessary strength if instead fabricated from cortical bone.

Appellants argue that neither Coates nor Siebels specifically describes pins made from cortical bone as recited in claim 115. App. Br. 44-46. Appellants also argue that neither Coates nor Siebels specifically describes pins made from cancellous bone treated with a bone morphogenetic protein (BMP) as required by claim 124. App. Br. 46-48. Again, the test for obviousness is not whether the claimed invention is expressly suggested in any one or all of the references. Nonobviousness cannot be established by attacking the references individually when the rejection is predicated upon a combination of prior art disclosures. *See In re Merck & Co. Inc.*, 800 F.2d 1091, 1097, (Fed. Cir. 1986). Siebels demonstrates the technique of

assembling multiple pieces and pins. It is not required that those pieces and pins must also be present in Coates in order to sustain a rejection under 35 U.S.C. § 103(a). The combined teachings of Siebels and Coates would have suggested that the components of the Siebels implant, namely the disks and pins, could be employed to construct the cortical bone implant taught by Coates. Similarly, Coates demonstrates that it was known to use cancellous bone and BMP in conjunction with implants of this nature. *See* Facts 2 and 3. That Coates points out the disadvantages of cancellous bone used without a supporting structure would not lead one of ordinary skill in the art away from using cancellous bone in conjunction with a structure that can provide the necessary support, such as one made from cortical bone exhibiting a high compressive strength. The combined teachings of Siebels and Coates would have suggested if Siebels' technique were used to fabricate the Coates implant, certain portions such as the pins, could be constructed from cancellous bone. Furthermore, Coates' teaching to apply BMP to a portion of, or the entire implant (Fact 3) would have suggested application to the pins if the implant were fabricated using Siebels' technique. An obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418.

Regarding claim 122, Siebels teaches manufacturing the implant to any necessary height. Fact 8. It would have been obvious to one of ordinary skill in the art to manufacture the implant to a height between 7 and 14 mm if that were the amount of space in the patient that the implant needed to occupy in order to perform a successful spinal fusion. Minor differences

between the prior art and a claimed device may be a matter of design choice absent evidence to the contrary. *See In re Rice*, 341 F.2d 309, 314 (CCPA 1965).

CONCLUSIONS OF LAW

For the above reasons, Appellants have not established that the Examiner erred in concluding that the subject matter of claim 111 would have been obvious to one having ordinary skill in the art based on Siebels and Coates. Appellants have not established that the Examiner erred in concluding that the subject matter of claim 115 would have been obvious to one having ordinary skill in the art based on Siebels and Coates. Appellants have not established that the Examiner erred in concluding that the subject matter of claim 124 would have been obvious to one having ordinary skill in the art based on Siebels and Coates. Appellants have not established that the Examiner erred in concluding that the subject matter of claim 122 would have been obvious to one having ordinary skill in the art based on Siebels and Coates.

REGARDING THE REJECTION OF CLAIMS 126-128 AS BEING UNPATENTABLE OVER BRANTIGAN AND COATES

ISSUES

Appellants acknowledge that unlike claim 111, claim 126 does not recite a “circular” through hole. Reply Br. 7. Appellants assert that Brantigan does not disclose through holes or retention pins of appropriate

diameter for fitting said through holes. Appellants do not separately argue claim 127. Claim 127 will therefore stand or fall with claim 126. Thus the first issue for our consideration is whether Appellants have established that the Examiner erred in determining that the subject matter of claim 126 would have been obvious because Brantigan does not disclose through holes or retention pins of appropriate diameter for fitting said through holes.

Appellants additionally argue that there would be no reasonable expectation of success in combining the teachings of Brantigan and Coates in the manner proposed by the Examiner. App. Br. 48-53. In light of this contention we must determine whether Appellants have established that the Examiner erred in determining that the subject matter of claim 126 would have been obvious because one of ordinary skill in the art would not have had a reasonable expectation of success in combining the relevant teachings of Brantigan and Coates.

Appellants additionally argue that neither Brantigan nor Coates specifically teaches a pin made from cancellous bone and treated with BMP. App. Br. 56-59. Thus, we must determine whether Appellants have established that the Examiner erred in determining that the subject matter of claim 128 would have been obvious because neither Brantigan nor Coates specifically teaches a pin made from cancellous bone and treated with BMP.

FINDINGS OF FACT

14. Brantigan discloses a D-shaped assembled implant 25 for implantation into a patient. Col. 5, ll. 8-11, 30-35.

15. Brantigan discloses the assembled implant 25 is formed by superimposing first and second D-shaped portions 21 having a through hole 21d. Col. 4, l. 57 – col. 5, l. 21; figs. 2, 5.
16. Although the through hole formed in Brantigan's stack receives a connecting bar 15, it is capable of receiving a retention pin for retaining the portions in stacked formation.
17. Brantigan fails to disclose that the implant is made from cortical bone portions.
18. Coates teaches that because cortical bone exhibits high compressive strength as compared to other bone graft materials, it is a preferred material for use in constructing intravertebral implants 110.
19. Coates teaches that fabricating an implant from biological materials, such as bone, is an improvement on devices such as Brantigan's which use foreign material such as metal. Coates teaches that it is advantageous to use biological material such as bone to fabricate an implant because bone is less stiff which discourages shielding, less likely to subside, and can become fully incorporated into the fusion mass. Col. 2, ll. 40-65.
20. Coates suggests making implants any suitable size or shape and recognizes that cortical bone may be shaped to the desired configuration by conventional machining methods adapted to bone in a known manner. Coates, col. 11, ll. 52-64.
21. Coates does not criticize or discredit fabricating the implant from multiple pieces.

PRINCIPLES OF LAW

A patent applicant is free to recite features of an apparatus either structurally or functionally. *See In re Swinehart*, 439 F.2d 210, 212 (CCPA 1971) (“[T]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims.”). Yet, choosing to define an element functionally, i.e., by what it does, carries with it a risk. *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997). As stated in *Swinehart*:

where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

439 F.2d at 213. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *See e.g., In re Schreiber*, 128 F.3d at 1477-78.

“35 U.S.C. § 103 forbids issuance of a patent when ‘the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.’” *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3)

the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). *See also KSR*, 550 U.S. at 407.

ANALYSIS

Appellants' argument that Brantigan does not disclose a "through hole" as recited in claim 126 is unpersuasive. Appellants have not provided any reason why, when stacked, apertures 21d are not reasonably read as forming the claimed "through hole" in the implant 25. Appellants' argument that Brantigan does not disclose retention pins of appropriate diameter for fitting said through holes is based upon a limitation that is not claimed. Claim 126 only requires that the through holes are sized and positioned for receiving a retention pin; the claim does not require a pin itself. Appellants have not established that Brantigan's through hole would be incapable of receiving a retention pin that could retain the implant portions in a stacked formation. *See Fact 16; See also In re Swinehart*, 439 F.2d at 212

Brantigan discloses the basic structure of the implant described but fails to disclose that it may be fabricated from cortical bone. Facts 14-17. Coates teaches that it was known in the art to use cortical bone to fabricate spinal implants. Fact 18. Constructing Brantigan's implant from cortical bone amounts to applying a known technique to improve a known device in order to yield the predictable result of proving an implant that is less stiff which discourages shielding, less likely to subside, and can become fully incorporated into the fusion mass. *See Fact 19*. For these reasons, this combination would have been obvious to one having ordinary skill in the art.

Appellants' argument that there would not have been a reasonable expectation of success in the proposed combination of Brantigan and Coates

is not persuasive. The fact that Brantigan itself does not disclose using bone does not establish that the Examiner erred in concluding that the claimed subject matter would have been obvious based upon a combination of Brantigan and Coates. App. Br. 49-50. While Coates may not teach bone as a substitute for metal in all applications (App. Br. 51), it suggests that some existing metal implants may be modified in such a way, specifically mentioning Brantigan's. *See* Fact 19. Coates also suggests that bone may be machined in a known manner in order to produce implants of a variety of sizes and shapes. Fact 20. These suggestions would have provided one of ordinary skill in the art with a reasonable expectation that Brantigan's device could be modified according to Coates' teaching of using bone to fabricate implants. The fact that Coates makes an implant out of a single piece does not establish that the Examiner erred in concluding that the claimed subject matter would have been obvious based upon a combination of Brantigan and Coates. Nor does it criticize or discredit a multi-piece implant. App. Br. 51-53; Fact 21.

Appellant has not established how making the pin from cancellous bone or treating it with BMP, as described in claim 128, would result in a structural distinction from parent claim 126 since the pin is not positively recited in either claim. App. Br. 46-47. Since Brantigan's implant would be capable of performing the recited function of receiving a cancellous bone retention pin treated with BMP for retaining the portions in stacked formation, it meets the claim's limitations. *See* Fact 16.

CONCLUSION OF LAW

Appellants have not established that the Examiner erred in determining that the subject matter of claim 126, and therefore claim 127, would have been obvious over Brantigan and Coates because Brantigan does not disclose through holes or retention pins of appropriate diameter for fitting said through holes. Appellants have not established that the Examiner erred in determining that the subject matter of claim 126 would have been obvious because one of ordinary skill in the art would not have had a reasonable expectation of success in combining the relevant teachings of Brantigan and Coates. Appellants have not established that the Examiner erred in determining that the subject matter of claim 128 would have been obvious because, neither Brantigan nor Coates specifically teaches a pin made from cancellous bone and treated with BMP

DECISION

For the above reasons, the rejection of claims 111-118, 120-123, and 129-136 as being anticipated by Albee is reversed. The rejection of claims 111-118, 120-125, and 129-136 as being unpatentable over Brantigan and Coates is reversed. The rejection of claims 111-118, 120-136 as being unpatentable over Coates and Siebels is affirmed. The rejection of claims 126-128 as being unpatentable over Brantigan and Coates is affirmed.

Appeal 2009-014427
Application 09/905,683

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). See 37 C.F.R. § 1.136(a)(1)(iv) (2007).

AFFIRMED

Vsh

REGENERATION TECHNOLOGIES, INC.
c/o MCANDREWS, HELD & MALLOY
500 WEST MADISON STREET
34TH FLOOR
CHICAGO IL 60661